

REMARKS/ARGUMENTS

Following entry of the present Response and Amendment, claims 1-66, and 80-121 remain in this application, with claims 1, 37 and 57 being written in independent format.

With respect to prior art, the Office Action rejected claims 1-5, 28, 32, 36-39, 50-58, 62-65, 80-83 and 88-97, 103-109, 114-120, 126 and 127 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,422,240 to Levitsky et al. (henceforth "Levitsky") in view of U.S. Patent No. 6,439,234 to Curti et al. (henceforth "Curti"). Further, the Office Action rejected claims 16-20 and 59 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,626,131 to Chua et al. (henceforth "Chua"). Also, claims 21-26 and 60-61 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 6,467,477 to Frank et al. (henceforth "Frank"). Finally, the Office Action rejected claims 46-49 and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 4,602,644 to DiBenedetto et al. (henceforth "DiBenedetto").

Claims 10-14, 27, 29-31, 33-35, 40-45, 84-86, 98-102, 110-113 and 121-125 were indicated as being directed to allowable subject matter, but were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims.

In the present Response and Amendment, claims 1, 11-12, 14, 37-38, 40, 48, 55-57, 64, 66, 80, 84-85 and 88 have been amended. Claims 1-5, 10-14, 16-66, and 80-127, as amended, still remain in the application. These amendments to the claims have been introduced to clarify the subject matter of the present invention, and to place the present application in better condition for allowance.

Applicant submits that the above-requested amendments do not add prohibited new subject matter, and respectfully requests reconsideration of the merits of the present application in accordance with these amendments and the following remarks.

Claim Rejections

Each of the grounds for claim rejections is addressed below.

35 U.S.C. § 103(a) – applying Levitsky and Curti

Claims 1-9, 15, 28, 32, 36-39, 50-58, 62-65, 80-83 and 88-92 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over Levitsky as modified in light of Curti. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

Specifically in regard to independent claims 1, 37 and 57 as previously presented, the Office Action contends in pertinent part that Levitsky teaches placing an oronasal cannula device in an area between a nose and mouth of a person where the cannula device has prongs for collecting expired gases individually from each nostril and from the mouth. In support of its incorrect conclusion that Levitsky teaches individual collection of the gases, the Office Action specifically and preemptively notes that “the prongs collect gases individually initially prior to the Y-shaped junction.” The Office Action further contends that Levitsky discloses an analyzer for the expired gas stream, and the use of a CO₂ sensor to measure CO₂ presence.

The Office Action admits that Levitsky does not teach detecting when a person is inhaling or exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase, but alleges that Curti can be combined with Levitsky to overcome this deficiency. Applicant believes this obviousness rejection, insofar as it applies to the present claims, is wholly inappropriate for various reasons and traverses as follows.

As noted in Applicant’s prior Response and Amendment, Levitsky pertains to cannula-type device for collecting expired gases from a patient with the purported benefit of reducing void volume within expired gas sampling lines (and thus eliminating problems in analysis caused by mixing, dilution collected samples). The Levitsky cannula, as recognized by the Office Action, includes a Y-shaped junction located between the nose and mouth where the tubes of the two nasal prongs and of an oral prong meet with a collection tube. The collection tube thereafter carries the gas to a downstream analyzer. An oxygen delivery tube, adapted to lie across the upper lip of the patient, is also disclosed. This delivery tube has two holes oriented below the nose of the patient intended to direct oxygen flow upward through a screen and to the nostrils of the patient for inhalation. Notably, as indicated in the Office Action, Levitsky does not address modulating the flow of delivered gas in any way.

Curti, which the Office Action purports to combine with Levitsky, discloses a split-nare type oronasal device that has a single fluid conduit for introduction up each nostril of the patient. One of the nasal prongs is connected to an oxygen source while the second nasal prong is connected to a gas analyzer – these prongs are not in communication and cannot be given the purposeful split-nare design of Curti. This separation of the nares in such a cannula is specifically addressed in the background portion of Applicant's specification at page 6, line 10, and within Levitsky at column 2, lines 28-47, and is described in both places as being undesirable in that it does not readily permit automatic control of sampling from various respiratory sites or account for the possibility that one nostril may be completely or partially obstructed compared to the other nostril, leading to poor oxygen delivery or sampling results.

Furthermore, Levitsky patent explicitly identifies and distinguishes the Curti patent, criticizes its contents and disassociates its structure and functioning with that of Curti. For example, at line 57, column 1 of Levitsky, it identifies Curti as the patent of "Salter Labs, Arvin Calif, USA". Levitsky further describes the Curti structure at line 13, Col. 7 and at Figure 3 of his own patent. Levitsky then specifically criticizes Curti concluding that its concept is unable to "collect gases for a completely accurate analysis."

Now, contrary to the express teaching away provided by Levitsky, the Office Action has completely ignored the structural distinctions pointed out by the Applicant and has elected to combine these references as a basis for rejecting the present invention. The fact that, as pointed out in Applicant's prior response, the devices of Levitsky and Curti are two completely different approaches that cannot be physically combined without the benefit of Applicant's teachings to form a product according to Applicant's claims. That the Office Action acknowledges these distinctions but then nonetheless still purports to combine these references is in violation of settled patent law. See MPEP sec. 2145 (III) (stating that a "combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose") and MPEP 2145 (X)(D) (citing *In re Greasselli*, 713 F.2d 731 (Fed. Cir. 1983) for the proposition that it is improper to combine references where the references teach away from their combination).

Contrary to the Office Action's position, there is no rational basis for ignoring Levitsky's distinction, criticism and disassociation of Curti and then combining with Livitsky

the very reference he criticized and from which its structure is disassociated. Therefore, not only is there no factual basis for combining these very different references (as described previously and revisited again below), but there is no legal basis for doing so. Indeed, the law conversely precludes such a combination. “When prior art references require selective combination by the court to render obvious a subsequent invention there must be some reason for the combination other than the hindsight gleaned from the invention itself. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n.4, 221 USPQ 929, 933 & n. 4 (Fed. Cir. 1984). There must be ‘something in the prior art to suggest the desirability, and thus the obviousness, of making the combination’. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984).” An accurate reading of Levitsky will produce no basis for combining its content with that of Curti, but instead will find reasons contradicting such a combination.

Removal of all rejections based upon the improper combination of Curti and Levitsky is thus respectfully requested.

Additionally, even if, *arguendo*, Levitsky and Curto could somehow be combined into an operable device, the fact also remains that such combination would still not render Applicant’s claims obvious as the “Y-shaped junction” brushed off in the Office Action clearly prevents one from collect gases individually. Various embodiments of Applicant’s invention, conversely, provide the ability to account for obstructed airways with prongs having fluid inlets that permit, as recited in claim 1, the collection of “expired gases individually from each of the two nares of the nose and from the mouth.” This feature allows preferred embodiments of the invention, such as are recited, for example, in dependent claims 10-13, 27, 40, 43, 84-87, and 122 (reciting analyzing only expired gases from unobstructed nares or separate analysis of the nose and the mouth) and dependent claims 43-44, 100, 112 and 123 (reciting the use of two capnometers to analyze nose and mouth expired gases independently), to monitor and/or analyze each breath stream independently for monitoring ventilation, determining the breathing cycle, and/or for expired gas concentration sampling. The cannulas taught by both Levitsky and Curti do not provide this capability as an option, and in fact cannot provide this capability due to their inherent designs. Specifically, as depicted in FIG. 4, Levitsky combines the collected gas streams from its two nostril prongs

with its single mouth prong at a Y-shaped junction immediately below the nose of the patient.
In this manner, gases from the mouth and both nostrils are immediately mixed before the
expired gases can be utilized to detect breathing or analyze respiration.

Similarly, Curti does not disclose a cannula having portions extending for insertion
into the nose and having fluid inlets that permit the collection of expired gases individually
from each of the two nares of the nose and from the mouth. The two nasal fluid conduits
disclosed in Curti serve different purposes, with only one conduit positioned in a single
nostril being utilized to collect expired gases (an no mouth fluid conduit being disclosed).
Thus, individual collection of expired gases cannot be disclosed, taught, or suggested by Curti
either, rendering any combination of Levitsky and Curti defective to teach the present
invention as recited in claim 1.

Further, claim 1 as presently amended recites that the fluid inlets for the particular
nasal prongs are in communication with a sensor for detecting when said person is inhaling
and exhaling. Levitsky does not disclose in any way the need to detect or how to detect when
a patient is inhaling. Contrary to the assertions in the Office Action, Curti similarly does not
disclose how to do such monitoring. While the referenced portion of Curti describes that its
particular split-nare type cannula can be utilized with an intermittent oxygen delivery system
that is adapted to provide oxygen only during inhalation, Curti does not describe any structure
to perform that function. (Nor does U.S. Patent No. 5,626,131 cited within cited portion of
Curti, and, coincidentally, also being invented by Chua et al. and having a substantially
similar disclosure to the Chua reference relied upon in the Office Action.) In fact, the main
focus of the Curti disclosure is centered on the use of holes within the walls of nasal prongs in
a cannula to prevent occlusion and/or clogging of the nasal prongs during use. The specific
structure as claimed by the Applicant cannot be rendered obvious merely by Curti baldly
stating that its invention could somehow be modified to provide for intermittent oxygen
delivery, or without some suggestion to one skilled in the art how to modify the simple
sampling system as disclosed in Levitsky so as to produce the structure and perform the steps
according to the present invention.

For these reasons, Curti cannot be considered to teach one skilled in the art how to
modify Levitsky to produce Applicant's claimed invention. As such, claim 1 and all claims

being dependent therefrom are patentable over the combination of Levitsky and Curti for these reasons alone.

Claim 37 as presently amended pertains to an apparatus for providing inspired gas to a person and samples expired gases from the person which includes an inspired gas delivery device and an oronasal device having portions extending into each nostril and for the mouth. Like claim 1, claim 37 recites the requirement that the prongs each have fluid inlets adapted to collect expired gases individually from the streams of expired gas emanating from each nare of the nose and from the mouth. Claim 37 further recites that the nare fluid inlets are in communication with a sensor that generates signals to said controller indicating when said person is inhaling and exhaling, and that the oronasal device is in fluid communication with a supply lumen providing supplied gas from the delivery device. As described above with respect to claim 1, neither Levitsky or Curti will be understood by one skilled in the art to collectively teach or suggest these features of the invention. Thus, claim 37 and all dependent claims are allowable over the prior art.

With regard to claim 57 as presently amended, Applicant has recited that inspired gas is supplied to the person using a cannula, and that the inspired gas is delivered through a plurality of holes located immediately about and partially surrounding the base of the nare prongs. As depicted and described in Applicant's specification at, for example, FIG. 10 and accompanying text, the arrangement of the plurality of fluid outlet holes immediately about the base of each portion that extends into the nares. These features of the invention, as taught in the specification, provide for inspired gas flow that is diffuse so as to avoid discomfort, but which is also sufficiently directed and localized to the area proximate to the nares to minimize waste of inspired gas to the atmosphere.

In an apparent attempt to address these claim limitations, the Office Action alleges that, since Levitsky shows a porous "pair of second nasal prongs 102" (See Levitsky, column 9) that serve to provide oxygen delivery to the patient's nose, this inherently discloses "fluid outlet holes ... located immediately about a base of and partially surrounding" the portions extending into the nares, as is recited by Applicant. A proper reading of Levitsky demonstrates that this is an unsupportable stretch of that reference's teachings. First, Levitsky makes clear that the element 102 is a separate prong that sits next to the nasal

collection prong 98. Thus, the prong in no way can be characterized as “partially surrounding” the base of collection prong 98. Second, since the pores of prongs 102, which the Office Action somehow equates to Applicant’s fluid outlet holes, are located on the prong and nowhere else, these pores cannot be said to partially surround the collection prong 98. Further, neither Levitsky or any other prior art of record provides any rationale to produce fluid outlet holes as claimed by the Applicant. Therefore, claim 57 and claims dependent therefrom are allowable over the cited art for this reason alone.

In light of the above remarks, Applicant respectfully requests reconsideration of all rejections based upon Levitsky and Curti. Applicant respectfully submits that these claims are allowable over the prior art, and appropriate reconsideration is requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Chua

Claims 16-20 and 59 were again rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Chua. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action contends that Chua discloses an oxygen delivery system that utilizes a pressure sensor for detecting whether the person is inhaling, and concludes that the teachings of Chua could therefore be combined with Levitsky and Curti to produce Applicant’s claimed invention. Applicant respectfully submits that Chua does not remedy any of the above deficiencies described immediately above with respect to the combined teachings of Levitsky and Curti, and therefore cannot render the present claims obvious.

Specifically, while Chua may relate to the use of pressure analyzers to determine when a patient is inhaling/exhaling in order to control oxygen delivery, it provides no description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery as is claimed by the Applicant. Chua merely describes what it considers to be the optimal manner of timing the increase and decrease of oxygen delivery in an intermittent delivery system. Applicant has not found, nor has the Office Action cited, any teaching present in any of Levitsky, Curti or Chua would lead one skilled in the art to produce Applicant’s oronasal structure as claimed. Therefore, in no

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way can the combination of these three references be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Frank

Claims 20-26 and 60-61 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Frank. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that Frank teaches the use of a humidity sensor and temperature sensor to detect whether the person is inhaling. Even if Frank discloses the use of humidity and temperature sensors to determine when a patient is inhaling/exhaling, that reference does not provide description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery, including the particular structure and steps discussed above with respect to the rejections base upon the combination of Levitsky and Curti. Therefore, the combination of these three references cannot be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and DiBenedetto

Claims 46-49 and 66 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of DiBenedetto. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that DiBenedetto teaches the use of a microphone to amplify a person's breathing to determine a respiratory phase. Even if DiBenedetto does teach how to use sound to determine a respiratory phase, this does not teach the invention as recited in claims 48, 49 and 66, so applicant respectfully traverses as follows.

Claims 48 and 49 depend from claim 37, and are thus allowable over the art for all the reasons discussed above with respect to the deficiencies of the combined teachings of

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Levitsky and Curti. Additionally, claim 48 (upon which 49 depends) recites the additional element of an auditory breath sonification device that includes a white noise generator that provides simulated breath sounds. Nowhere does DiBenedetto teach a white noise generator for providing simulated sounds. DiBenedetto uses a whistle-like sensor device for determining whether a patient is inhaling or exhaling according to the sound waves created by the breath stream's interaction with that sensor. It does not determine breathing, and then create simulated breathing sounds as is claimed.

Again, as in the last Response and Amendment, Applicant also points out that claim 66 recites the novel and nonobvious addition of a sound lumen to the claimed cannula. The sound lumen connects the person to an auditory device that can create sounds for transmission to the person such that said sound lumen functions as a stimulus channel that carries an auditory prompt to the person. In no way does DiBenedetto discuss transmitting sound to the person for any reason.

Appropriate reconsideration of rejections based in part upon DiBenedetto is thus requested.

Allowable Claims

Claims 10-14, 27, 29-31, 33-35, 40-45, 84-86, 98-102, 110-113 and 121-125 were indicated by the Office Action as being directed to allowable subject matter, and were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims. Applicant thanks the Examiner for the indication of allowable subject matter in this application.

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Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the above-noted Response and Amendment when the claims are re-examined on its merits. A timely allowance of the pending claims is requested.

This Response and Amendment is being transmitted concurrently along with a Request for Continued Examination, which is also serving as a constructive petition for extension of time. A check is submitted herewith in an amount believed sufficient to cover these fees.

If the amount of the check is insufficient to cover the required additional claims and extension of time fees, or is in excess of the required cumulative fee, please charge any necessary fees and/or credit any overpayments to Deposit Account No. 50-1349.

Additionally, if there are any other fees due in connection with the filing of this Response and Amendment that are not covered by the enclosed check please charge those other fees to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

Respectfully submitted,

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HOGAN & HARTSON LLP
555 13th Street, N.W.
Washington, D.C. 20004
Telephone: 202-637-5600
Facsimile: 202-637-5910
Customer No. 24633

By:


Celine Jimenez Crowson
Registration No. 40,357

Kevin G. Shaw
Registration No. 43,110